James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

I. INTRODUCTION

Bard reiterates what it said at the outset: This preemption case is different. No court has addressed preemption where a 510(k)-cleared device has the kind of developed factual record, special controls, device-specific Guidances, history of down classification, and extensive regulatory review associated with Bard's IVC filters. Plaintiffs, of course, insist that this case is just "typical" 510(k) review, because it serves their purpose to ignore the relevant facts. Thus, they offer no facts or authority to support their position.

In contrast, Bard has demonstrated how its extensive IVC filter regulatory history differs from most 510(k) devices, especially the device in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Any honest review of the regulatory history here demonstrates that FDA imposed exactly the sort of device-specific federal requirements for design, manufacture, testing, and labeling of Bard's IVC filters that Justice Breyer's majority-making concurrence found would support preemption in *Lohr*. Thus, *Lohr* "disclaimed a conclusion that general federal requirements could never pre-empt" and held only "that no pre-emption occurred in the case at hand based on a careful comparison between the state and federal duties at issue." *Riegel v. Medtronic, Inc.*, 553 U.S. 312, 322 (2008) (discussing *Lohr*, 518 U.S. at 500-01). As Justice Neil Gorsuch recognized in *Caplinger v. Medtronic, Inc.*, for preemption to exist, "a device must undergo the premarket approval process—or, [as] the Court [in *Lohr*] suggested, perhaps something like it." 784 F.3d 1335, 1340 (10th Cir. 2015). FDA has confirmed the centrality of safety and effectiveness in the modern 510(k) process, and its rigorous review of Bard's IVC filters, described in detail in Bard's exhibits and opening brief, is precisely the scenario that Justices Breyer and Gorsuch contemplated would impose federal requirements authorizing preemption.

II. ARGUMENT AND CITATION TO AUTHORITIES

A. The Government Weighed Competing Interests and Imposed Device-Specific Federal Requirements on Bard Via Special Controls and a PMA-Like Regulatory Review.

Plaintiffs acknowledge that preemptive federal requirements arise when FDA "has weighed the competing interests relevant to the particular requirement in question,

reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." (Pls. Br. at 13 (quoting *Lohr*, 518 U.S. at 501).) Suggesting that such weighing occurs only with PMA devices, they emphasize the "contrast" between PMA and 510(k) made in *Lohr*—that "510(k)-cleared devices still 'may be marketed without advance [FDA] approval.'" (*Id.* (quoting *Lohr*, 518 U.S. at 477).) The FDA, however, imposed precisely the sort of mandate in this case that Plaintiffs admit triggers preemption. The extensive FDA regulatory record here is the antithesis of *Lohr*'s distinction. None of Bard's IVC filters can conceivably be described as "marketed without advance approval." Preemption therefore bars Plaintiffs' claims.

1. **FDA's Down-Classification Memos Prove This Case Is Different**.

FDA originally classified IVC filters as Class III devices. *See* 45 Fed. Reg. 17736 (FDA Feb. 5, 1980). In 1995, FDA required IVC filter manufacturers to submit summaries of known safety and effectiveness information for FDA to determine whether to reclassify them as Class II. 60 Fed. Reg. 41986 (FDA Aug. 14, 1995); (Decl. C. Polston, Ex. H, *Reclassification of Cardiovascular Intravascular Filters* (FDA Dec. 2, 1996), at BPV-17-01-00262283-284.)[1] On July 22, 1996, Nitinol Medical Technologies ("NMT") submitted the requested information. (Ex. H, at BPV-17-01-00262284.)

On December 2, 1996, after an "extensive review" of all the publicly available information, MDRs, previously cleared 510(k)s, and the information submitted by NMT and other manufacturers, FDA identified all of the known safety and efficacy concerns for IVC filters, including the risks at issue in this litigation: death, migration, penetration, tilt, embolization, and fracture. (*Id.* at BPV-17-01-00262286-289.) FDA found that, "[a]lthough these risks are potentially life threatening, as is the disease they are intended to treat, they are well known to the users and are well characterized in the medical

[1] Bard obtained this internal FDA material on August 12, 2017 from the PACER docket for the Cook IVC Filter Litigation, 1:14-ml-2570-RLY-TAB (Doc. 5728-1). Members of the Plaintiffs' Steering Committee are also involved in that litigation. Bard produced these materials to Plaintiffs in this litigation on August 18, 2017.

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
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literature." (*Id.* at BPV-17-01-00262285). FDA also identified the competing benefits of IVC filter use. (*Id.* at BPV-17-01-00262289-290).

Weighing benefits against risks that "have been well characterized" over the long history of IVC filter use, FDA concluded "that the use of [IVC filters for certain indications] does not present a potential unreasonable risk of illness and injury, and that special controls would ***provide reasonable assurance of the safety and effectiveness of the device***." (*Id.* at BPV-17-01-00262285-286 (emphasis added).) "Although placement of IVC filters are not without risks, the likelihood of risks occurring is relatively small and special controls will further minimize these occurrences." (*Id.* at BPV-17-01-00262290.) "Special controls in the form of standardized labeling and a device [Guidance] on vena cava filters. . ., in addition to general controls, ***provide reasonable assurance of the safety and effectiveness of the device***." (*Id.* at BPV-17-01-00262285 (emphasis added).) Thus, FDA concluded, "based on publicly available, valid scientific evidence, the [IVC] filter can be regulated as a Class II device (general and special controls) to ***reasonably assure that the device is safe and effective for its intended use***." (*Id.* at BPV-17-01-00262290 (emphasis added).) This "rigorous" "reasonable assurance" standard was recognized as preemptive by both *Riegel* and *Lohr*. *Riegel*, 552 U.S. at 323; *Lohr*, 518 U.S. at 477.

In 2000, FDA published its final rule reclassifying IVC filters from Class III to Class II. 65 Fed. Reg. 17138, 17144 (FDA Mar. 31, 2000). This rule amended 21 C.F.R. §870.3775[2] to identify IVC filters as Class II devices and incorporated special controls into this counterpart regulation,[3] including the device-specific Filter Guidance. (Defs.

[2] Plaintiffs argue that 21 C.F.R. §870.3375 is merely an identification regulation imposing no substantive federal requirements. (Pls. Br. at 12.) Plaintiffs cite inapposite pre-SMDA cases, none of which involved regulations imposing "special controls," as here. *See Anguiano v. E.I. Du Pont De Nemours & Co., Inc.*, 44 F.3d 806, 810 (9th Cir. 1995) (21 C.F.R. §§872.3680, 874.3695, 878.3500); *Ginochio v. Surgikos, Inc.*, 864 F. Supp. 948, 953 (N.D. Cal. 1994) (21 C.F.R. §888.3560); *Elbert v. Howmedica, Inc.*, 841 F. Supp. 327, 331 (D. Haw. 1993) (21 C.F.R. §888.3560). FDA considers "[s]pecial controls [as] regulatory requirements" that "are device-specific." (Defs. SSOF ¶ 26.)

[3] Plaintiffs argue that, in an unrelated state court matter, Bard "claimed that whether safety and efficacy underlie the 510(k) process creates a genuine issue of fact precluding summary judgment." (Pls. Br. at 5 n.6.) Plaintiffs wrongly conflate this supposed "admission" with an issue of fact here. (*Id.*) *Austin* did not involve preemption, only a state law compliance defense, and Bard consistently argued in *Austin* that safety and

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Atlanta, GA 30363
(404) 322-6000

SSOF ¶ 29.) To prepare the Filter Guidance, FDA reviewed previous IVC filter 510(k)s and IDEs and found "a set of consistent ***requirements*** in terms of ***required data***" that must be included in future 510(k) submissions. (Ex. H, at BPV-17-01-00262286 (emphasis added).) According to FDA, "[t]he guidance document will help to convey to manufacturers of these products the ***necessary*** in vitro, animal and human clinical data ***that will be necessary to support marketing clearance***." (*Id.* (emphasis added).) The FDA Guidance included standardized labeling and "***mandated***" warning statements. (*Id.*)

This, then, ***is*** a case, unlike *Lohr*, where FDA "has weighed the competing interests" and unambiguously resolved those interests in favor of implementing "a specific mandate" on Bard. *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) (citing *Lohr*, 518 U.S. at 501). Unlike *Lohr*'s generic federal requirements, the specific requirements FDA imposed on Bard's IVC filters via device-specific special controls—not present in the 510(k) process *Lohr* considered—and FDA's enforcement of those controls throughout its regulatory review of Bard's 510(k) submissions, reflect "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Lohr*, 518 U.S. at 501.

2. **The IVC Filter Guidance Is a Device-Specific Federal Requirement**.

The Ninth Circuit and other courts recognized special controls like those in 21 C.F.R. §870.3375 as device-specific federal requirements. *Degelmannn v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 842 (9th Cir. 2011), *vacated*, 699 F.3d 1103 (9th Cir. 2012); *Tuttle v. CIBA Vision Corp.*, No. 2:05-CV-340 TS, 2007 WL 677134, at *2 (D. Utah Mar. 1, 2007). Both *Degelmann* and *Tuttle* held that FDA Guidance documents can be device-specific requirements having preemptive effect. Indeed, *Degelmann* found preemption even though the Guidance document explicitly permitted alternative approaches to satisfying the requirements. *Degelmann*, 659 F.3d at 842.

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effectiveness ***do*** underlie the 510(k) clearance process. (*See* Pls. SSOF, Ex. 2 at Ex. Z (*Austin* Hr'g Tr. at 46:20-22.).) Unlike preemption, which is a dispositive question of law, regulatory compliance is a common-law jury issue.

Here, FDA's Filter Guidance mandated important preclinical tests and clinical design requirements, which FDA enforced against Bard's IVC filters. (Defs. SSOF ¶¶ 32-34.)[4] It did so to ensure the "safety and effectiveness" of these devices. (*Id.* at Ex. F at 1.) The Guidance identified aspects of IVC filter design that "need to be addressed" through preclinical tests when seeking 510(k) clearance. (*Id.* at 3.) While the Filter Guidance might not be as verbose as that at issue in *Degelmann* and *Tuttle*, (Pls. SSOF, Ex. 2 at Ex. Y), FDA's implementation of the Filter Guidance here provided the same stringent review and the device-specific criteria that the courts in those cases found warranted preemption.

3. **Bard's IVC Filter Regulatory History Demonstrates How this Case Is Different and Is "Something Like" PMA Review**.

Bard's facts show that this case involves an elevated and exceptional level of FDA review imposing device-specific requirements. They include FDA-mandated compliance with: special controls specific to IVC filters; an FDA Guidance specific to IVC filters; extensive required clinical trials and testing; specific FDA labeling changes dictated word-for-word; and numerous detailed FDA requests for safety-related information that, if unanswered, would cause FDA to deem Bard's 510(k) submissions withdrawn.[5]

Plaintiffs nevertheless argue that Bard's regulatory history is "typical" of any other 510(k) device. (Pls. Br. at 1, 21.) They claim that post-SMDA FDA regulatory review of Bard's IVC filters was not equivalent to, or "something like," the PMA process. (*Id.* at 20,

[4] For a federal requirement to be "device-specific" for preemption, the requirement need only be specific to a device type, not a specific manufacturer's device within that device type. *See, e.g.*, *Degelmannn*, 659 F.3d 835 (all contact lens solution); *Papike*, 107 F.3d 737 (all tampons). Plaintiffs' insistence that 21 C.F.R. §870.3375 and the Filter Guidance were not "device-specific" because they were not limited to Bard's devices misses the point. (Pls. Br. at 18.) They are clearly specific to IVC filters, including Bard's.

[5] Plaintiffs object to portions of Bard's SSOF as inadmissible hearsay, particularly the FDA statements in certain documents. On summary judgment, the substance, not the form, of evidence is crucial. Where claimed hearsay "could be presented in an admissible form at trial," it may be considered on summary judgment. *Fraser v. Goodale*, 342 F.3d 1032, 1036-37 (9th Cir. 2003). Further, these documents or their contents would be admissible at trial under hearsay exceptions (i.e., as business records or present sense impressions), or are not hearsay in the first instance because they are only offered for their effect on the listener. *See, e.g.*, *U.S. v. Blechman*, 657 F.3d 1052, 1066 (10th Cir. 2011) (business records); *In re Cirrus Logic Sec. Litig.*, 946 F. Supp. 1446, 1469 (N.D. Cal. 1996) (present sense impression); *Wolf v. Travolta*, 167 F. Supp. 3d 1077, 1084 n.3 (C.D. Cal. 2016) (effect on the listener).

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

23.) These bald assertions are unsupported by meaningful facts or legal precedent. Plaintiffs identify no case approaching the level of FDA involvement established here—e.g., down classification, special controls, device-specific FDA guidance, clinical trial and data requirements, labeling changes, requests for additional testing and other information—that denied preemption to a manufacturer of a 510(k) device.

Failing to establish how this case is "typical" of 510(k) devices generally, Plaintiffs downplay the compelling evidence of these devices' uniqueness: FDA's repeated demands for clinical trials and data as a prerequisite for clearance of many of Bard's IVC filters. (*Id.* at 22-23.) Clinical trial requirements exemplify the "rigor" that makes FDA pre-market approval preemptive, *Riegel*, 552 U.S. at 343 & n.15, since, "[t]o receive premarket approval, a sponsor must conduct clinical trials that demonstrate the device's efficacy and safety." *Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 437 (6th Cir. 2014); *accord Horn v. Thoratec Corp.*, 376 F.3d 163, 169-70 (3d Cir. 2004) (pre-*Riegel*; years of clinical trials left "no doubt" that "the PMA process imposed requirements that were specifically applicable to the [device], and that triggered preemption"); *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1093 (D. Ariz. 2014) (preemption where PMA "was pending the completion of FDA-approved clinical trials") (following *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013)).

Likewise, clinical data requirements confer preemption because the investigational device requirements do not materially differ from the PMA process. *See, e.g.*, *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 227 (6th Cir. 2000) ("no material difference" between the IDE and PMA processes). That FDA required clinical trials as part of the 510(k) review elevates Bard's 510(k) submissions above the vast majority of 510(k) devices—especially over the device in *Lohr*. According to FDA statistics, "[l]ess than one percent of non–in-vitro-diagnostic 510(k)s reference a clinical trial conducted under an approved [IDE]." (Defs. SSOF ¶ 16.) Before the SMDA, clinical data were only required for PMA devices, demonstrating that Bard's filters received "something like" PMA review. (Mot. at 18-25.)

Bard's clinical studies were not "solely retrievability studies" as Plaintiffs assert.

(Pls. Br. at 23.) The EVEREST and Denali clinical studies addressed the safety and effectiveness of the G2 and Denali Filters by assessing rates of recurrent PE and new or worsening DVT, migration, fracture, tilt, and penetration. (Pls. SSOF, Ex. 2 at Ex. W (BPVE-502d-00000017); Defs. SSOF, Ex. B at Ex. 66g (BPV-17-01-00215976-80).) Nor does the ultimate completion of clinical studies after the FDA cleared the G2 Filter (for permanent indication) and the Denali Filter (for permanent and retrievable indications) impact the preemption analysis. (Pls. Br. at 22.) FDA made those clinical studies a prerequisite to clearance, and Bard included clinical data from those studies in its 510(k) submissions, which the FDA reviewed before clearing the devices. (Mot. at 22-23.)

B. Plaintiffs' Position Is Really that No Preemption Exists for Any 510(k) Device Absent a Counterpart Regulation.

Plaintiffs acknowledge three sources of preemptive federal requirements: (1) device-specific counterpart regulations; (2) federal safety review; and (3) device-specific requirements imposed on manufacturers after FDA has weighed competing interests. (Pls. Br. at 13.) They concede that express preemption protects a 510(k) device subject to device-specific counterpart regulations (although denying that special controls in identification regulations are preemptive). However, Plaintiffs invent a bright-line rule limiting preemption to these contexts, despite contrary authority. *See, e.g.*, *Riegel*, 552 U.S. at 322; *Lohr*, 518 U.S. at 503 (both eschewing "never pre-empt" positions); *Degelmann*, 659 F.3d at 842 (device-specific Guidance preemptive); *Tuttle*, 2007 WL 677134, at *2 (same). Nor does FDA agree with such a rule. In an *amicus curiae* brief filed earlier this month, the Agency argued that express preemption applies to any device "subject to device-specific federal requirements" even if it "did not receive [PMA]."[6]

As to 21 C.F.R. §808.1(d), the *Lohr* majority professed to be "informed" by its limitation of §360k(a) while following a "presumption against pre-emption." 518 U.S. at

[6] FDA *amicus curiae* submission at 10, *Shuker v. Smith & Nephew, Inc.*, No. 16-3785 (6th Cir. filed Sept. 14, 2017). Thus, while FDA (not addressing the SMDA) believes that 510(k) devices are not "generally" protected by preemption, *id.* at 7, it pointedly avoided any bright-line rule.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

485-85. That is no longer true, for two reasons. *First*, in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011), the Court clarified that "we do not defer to [FDA's] ultimate conclusion about whether state law should be pre-empted." *Id.* at 613. *Second*, as Bard discussed in its opening brief, the Court has since abolished the presumption against preemption in express preemption cases such as this. *Puerto Rico v. Franklin-Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016). Without artificial presumptions or deference, "§808.1(d)(1) can add nothing to our analysis but confusion." *Riegel*, 552 U.S. at 329.

Plaintiffs demand that the Court adopt their bright line rule that 510(k) review can ***never*** impose federal requirements because it is not PMA review, no matter how extensive the actual FDA review was. *Lohr*, they claim, "stated unequivocally that federal requirements are neither imposed nor created during the FDA's 510(k) pre-market notification review process." (Pls. Br. at 2.)[7] *Lohr* nowhere so held, rather "disclaim[ing that] conclusion." *Riegel*, 553 U.S. at 322. Justice Breyer (whose vote was required to make a majority) opined that "the MDA will sometimes pre-empt a state-law tort suit" concerning a 510(k) device. *Lohr*, 518 U.S. at 503; *accord Caplinger*, 784 F.3d at 1340 (for preemption to exist, "a device must undergo the premarket approval process—or, the Court [in *Lohr*] suggested, perhaps something like it.").

Bard demonstrated in its Motion how the post-SMDA 510(k) process that Bard's IVC filters underwent provided "safety review," (Mot. at 15-25), precluded "deviations" from FDA requirements, (*id.* at 28),[8] and provided "a reasonable assurance of safety and

[7] Plaintiffs mischaracterize 510(k) review as limited to "establish[ing] that the new device has the same intended use as the predicate device, and has the same technological characteristics." (Pls. Br. at 9.) Post-SMDA 510(k) also reviews if the device "has different technological characteristics and [if so whether] the information submitted . . . contains information, ***including clinical data if deemed necessary by the Secretary***, that demonstrates that the device is as ***safe and effective*** as a legally marketed device, and (II) does not raise different questions of ***safety and efficacy*** than the predicate device." PL 101-629 §12 (emphasis added).

[8] Plaintiffs misstate Bard's argument on its ability to unilaterally change its labeling. (Pls. Br. at 20 n.19.) Bard actually stated that it is "prohibited from unilateral labeling changes that ***significantly*** impact safety and effectiveness without first submitting a new 510(k)." (Mot. at 28 (emphasis added).) Bard does contend, however, that any labeling (or design) change that Plaintiffs might demand would necessarily require a label (or design) change that significantly affects the safety and effectiveness of the device, necessitating a new 510(k) submission. (*Id.*)

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effectiveness," (*id.* at 19; *see also infra* II.A.1)—the three attributes that the *Riegel* court found preemptive in the PMA context. *See* 552 U.S. at 323. Plaintiffs ask the Court to disregard the specific safety review that FDA performed on Bard's IVC filters—which was close to or "something like" PMA review—and hold that the 510(k) process itself can ***never*** preempt a 510(k) device. Plaintiffs' request is not supported by *Lohr*.

C. Dr. Kessler's Legal Conclusions Are Impermissible Expert Testimony.

Dr. Kessler's opinion on the legal import of FDA's "requirements" has no probative value. The controlling question is whether the FDA—via its regulations, guidance documents, and oversight activities—imposed device-specific requirements on Bard's IVC filters. *See Riegel*, 552 U.S. 312. "[P]reemption is predominantly a legal question, resolution of which would not be aided greatly by development of a more complete factual record." *Atay v. County of Maui*, 842 F.3d 688, 698 (9th Cir. 2016). Thus, "whether federal law preempts a state claim is a question of law for the court to decide and not for an expert to comment on." *Hovey v. Cook, Inc.*, No. 2:13-CV-18900, 2015 WL 1405565, at *20 (S.D.W. Va. Mar. 26, 2015).[9]

Dr. Kessler, who has not served in the FDA for 20 years, opines that the Filter Guidance did not establish specific requirements or recommendations. (Pls. SSOF ¶¶ 29-34; Pls. Ex. 1.D at ¶ 38.) He also opines that the "special controls for IVC filters did not assure" the absence of "new questions about safety and effectiveness" or "that the devices were safe and effective." (Pls. SSOF ¶ 48; Pls. Ex. 1.D at ¶ 45.) Dr. Kessler further opines that "[n]othing about" FDA mandating clinical data "elevated the FDA review of Bard's IVC filters beyond a 510(k) review for substantial equivalence." (Pls. SSOF ¶ 18; Pls. Ex. 1.D at ¶ 25.) All of this testimony goes to the legal import of FDA's "requirements." The Court needs no expert opinion to look at the law and decide whether FDA special controls

[9] *Accord Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 446 (D.N.J. 2003) (rejecting expert testimony because "whether the FDA's approval of a [device] imposes requirements on a particular device is a question of law to be determined by the Court.") Multiple courts likewise reject expert testimony on the legal effect of FDA regulations or activity. *E.g.*, *Livingston v. Wyeth, Inc.*, No. 1:03CV00919, 2006 WL 2129794, at *6 (M.D.N.C. July 28, 2006); *United States v. Caputo*, 374 F. Supp. 2d 632, 646 (N.D. Ill. 2005); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546-47 (S.D.N.Y. 2004).

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

and regulatory activities set specific requirements for Bard's IVC filters that have preemptive effect. As the Ninth Circuit succinctly held, "[r]esolving doubtful questions of law is the distinct and exclusive province of the trial judge." *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008). "Experts may interpret and analyze factual evidence but may not testify about the law." *S.E.C. v. Capital Consultants, LLC*, 397 F.3d 733, 749 (9th Cir. 2005). Thus, this testimony should not be considered.

D. Plaintiffs' Cited Legal Authorities are Inapposite.

As explained in Bard's Motion, *Lohr* and *Riegel* supply the analytical framework for this Court to assess preemption of Plaintiffs' claims under §360k(a). (Mot. at 9-14.) Court of Appeals decisions in *Perez*, *Degelmann* and *Caplinger* provide additional persuasive authority on applying preemption to the post-*Lohr* SMDA regulatory scheme at issue here. No court has considered a regulatory history similar to Bard's IVC filters.

Plaintiffs' cited authorities hardly compel rejection of preemption here. All of their cases are either: (a) factually distinguishable, (b) lack the necessary evidentiary record (unlike that before this Court), or (c) address other issues.

James v. Diva Int'l, Inc.: *James* decided a motion to dismiss with no factual record at all. *See* 803 F. Supp. 2d 945, 946-47 (S.D. Ind. 2011). The manufacturer relied only on general FDA quality system regulations ("QSRs"), foreign device regulations, and certain Canadian regulations as providing the preemption-creating "requirements." *Id.* at 950. *James* did not have what is before this Court: a developed factual record, device-specific special controls, and an FDA guidance document creating the device-specific requirements. *See id.*

Horillo v. Cook Inc.: Plaintiffs greatly overstate *Horillo*'s result, which found only a lack of "sufficient evidence" to support preemption. No. 08-60931-CIV, 2014 WL 8186704, at *3 (S.D. Fla. June 6, 2014). The record here lacks nothing. Far from disregarding *Lohr* and *Riegel*, Bard's argument employs that analytical framework to demonstrate that the regulatory history of Bard's IVC filters is within the preemptive "something like" PMA review. *Caplinger*, 784 F.3d at 1339 (analyzing *Lohr*, 518 U.S. at

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

498-99; *Riegel*, 552 U.S. at 322-23).

In re C. R. Bard, Inc. ("Cisson"): *Cisson* is not a preemption decision at all. Rather it decided, under an abuse-of-discretion standard, whether the trial court had properly excluded 510(k) evidence during a jury trial under Fed. R. Evid. 403. 810 F.3d 913, 919 (4th Cir. 2016).

Huskey v. Ethicon, Inc.: Preemption in *Huskey* did not involve the 510(k) process. 29 F. Supp. 3d 736, 746 (S.D.W. Va. 2014). To the contrary, it involved a PMA product (certain sutures), implanted in the plaintiff along with a 510(k) device, which was "a different medical device." *Id.* at 746-47.[10]

Placencia v. I-Flow Corp.: Presumably, Plaintiffs cite *Placencia* because this Court authored it. *Placencia* actually supports Bard's position that a "specific and detailed directive," such as an FDA guidance document, can support preemption of claims regarding a 510(k) device. No. CV10-2520 PHX DGC, 2012 WL 5877624, at *5 n.3 (D. Ariz. Nov. 20, 2012).

Thompson v. DePuy Orthopaedics, Inc.: Plaintiffs argue that, under *Thompson*, "[g]uidance documents assigned as special controls . . . cannot be deemed federal requirements." (Pls. Br. at 18 (citing *Thompson*).) *Thompson* made no such holding, instead recognizing that "special control documents may provide specific requirements, … that support a conclusion of preemption of state law claims." No. 1:13-CV-00602, 2015 WL 7888387, at *9 (S.D. Ohio Dec. 4, 2015). Although expressing some doubt over FDA guidance documents as federal "requirements," it did not reach that question, finding only that particular statements in a particular guidance document were "insufficient." *Id.* at *10. The defendant in *Thompson* did not contend that FDA 510(k) review of its product was "comparable to the PMA process." *Id.* at *9.

Oja v. Howmedica, Inc.: As with *Placencia*, *Oja* actually supports Bard's position.

[10] Further, *Huskey* followed a rigid, bright-line rule barring all preemption with respect to any 510(k) cleared device, *id.*at 746,—something the Supreme Court rejected in *Lohr* and *Riegel*, and Plaintiffs profess to disclaim. (May 3, 2017 Hr'g Tr. at 7-16 (Plaintiffs' counsel deny they advocate a bright-line rule).)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Oja held that FDA pre-510(k) clearance correspondence with a manufacturer—concerning a labeling requirement (prohibiting an indication for use)—did in fact "constitute[] a federal requirement applicable" to the device. 111 F.3d 782, 789 (10th Cir. 1997). Preemption failed for a different reason, that warning claims were not "positive enactments of state law" and, thus, could not be a state "requirement" preempted under §360k(a). *Id.* That narrow view of state "requirements" was rejected in *Riegel.* 552 U.S. at 329 (§360k(a) preempts "a state common-law requirement for additional warnings."). What *Oja* recognized as a preemptive FDA "requirement" is far less than the requirements demonstrated by the record here.

E. Plaintiffs' Allegations that Bard Did Not Share Information With FDA Are Irrelevant to the Preemption Analysis and Are Preempted under *Buckman*.

Plaintiffs allege that Bard did not share certain information with FDA but do not explain how these allegations impact the Court's preemption analysis. (*See* Pls. Br. at 23-25.) These allegations are irrelevant to the preemption analysis because they require the Court to speculate on what FDA would or would not have done had it received information that Plaintiffs allege should have been submitted. Court after court has held that *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), preempting allegations that FDA was defrauded during the 510(k) process, similarly preempts attacks on the quality of the information underlying FDA's decisions by plaintiffs opposing preemption. *E.g.*, *Estes v. Lanx, Inc.*, 660 F. Appx. 260, 262 (5th Cir. 2016); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1180 (S.D. Cal. 2016); *In re Incretin-Based Therapies Prod. Liab. Litig.*, 142 F. Supp. 3d 1108, 1130-31 (S.D. Cal. 2015). Plaintiffs cite no authority that a device otherwise entitled to preemption loses its preemption defense because information was not provided to FDA.

F. Plaintiffs' State Law Claims Are Expressly Preempted.

Because Plaintiffs' product liability claims would impose requirements different from or in addition to FDA's federal requirements, they are expressly preempted:

Manufacturing Defect (Counts I, V). Plaintiffs allege that Bard's IVC filters

were defectively manufactured because they supposedly had surface markings, and that Bard breached a duty of reasonable care by failing to adopt adequate manufacturing and quality assurance processes. (Compl. ¶¶ 85-86, 124, 169, 199-200.) Even if those markings did amount to manufacturing defects, Plaintiffs "have not identified any specific requirements" in Current Good Manufacturing Practices ("CGMPs") or QSRs, so that "[w]ithout any such specified requirement, Plaintiffs necessarily seek to impose requirements that differ from the CGMPs/QSR." *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (hereinafter "*Sprint Fidelis*"), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).[11] Plaintiffs' manufacturing defect claims are thus expressly preempted.

Design Defect (Counts III, IV). Plaintiffs allege that Bard's IVC filters were defective in design in that the "foreseeable risks exceeded the alleged benefits." (Compl. ¶ 186.) To prevail, Plaintiffs would have to establish that Bard's IVC filters should have a different design than FDA cleared after rigorous review of the clinical and pre-clinical testing of that design. *Arvizu v. Medtronic, Inc.*, 41 F. Supp. 3d 783, 792 (D. Ariz. 2014); *cf. Lohr*, 518 U.S. at 504 (claim that FDA-mandated "2-inch wire" should have been "1-inch" would be preempted) (Breyer, J. concurring). Plaintiffs' claims that Bard "fail[ed] to perform adequate evaluation and testing of Bard IVC Filters," (Compl. ¶¶ 195-196), also fail because FDA would not have cleared the devices had Bard's clinical and pre-clinical testing not adequately addressed the design issues described in the Filter Guidance, (Defs. SSOF ¶¶ 31-36), all of which FDA determined were sufficient to "provide a reasonable assurance of the safety and effectiveness of the device." (Ex. H, at BPV-17-01-00262285.) Nor would FDA have cleared the devices had Bard not performed the additional testing, including clinical testing, FDA required throughout its PMA-like review. (Defs. SSOF ¶¶ 43-47, 182-88, 205-07, 211-13, 384-85, 396, 442, 494-98, 524, 528-29, 538-39, 545-49,

[11] PMA cases are instructive because the federal specifications that FDA imposed here to provide "reasonable assurance of safety and effectiveness" constitute specific federal requirements that have similar preemptive effect to those established during the PMA process. *Riegel*, 552 U.S. at 323; *Lohr*, 518 U.S. at 477.

552-55, 602-608, 636-39, 661-62, 671.) Plaintiffs' design defect claims "would impose requirements that are different from or in addition to federal law," so they are expressly preempted. *Arvizu*, 41 F. Supp. 3d at 792.

Warnings (Counts II, VII). Plaintiffs allege that Bard's warnings failed to advise them or their physicians about safety and effectiveness issues: the rate of failure including as compared to other IVC filters, and the severity of the risks. (Compl. ¶¶ 165, 175, 212, 216.) To prevail, Plaintiffs would have to prove that Bard should have provided different or additional warnings from those FDA reviewed and cleared—and, for many of these devices, partially rewrote. (Defs. SSOF ¶¶ 73, 74, 77, 80, 82-97, 103, 111-12, 114, 190-91, 215, 227-31, 240, 253-55, 261, 463-64, 502, 530, 550, 556, 571-72, 640, 699, 754-58, 771, 776-77.)[12] For warnings "not imposed by federal law, [a] state law claim would therefore impose a duty different from or in addition to those imposed by the FDCA, contrary to the preemption provision in §360k." *Thibodeau v. Cochlear Ltd.*, No. CV-13-02184-PHX-DGC, 2014 WL 3700868, at *4 (D. Ariz. July 25, 2014). Plaintiffs concede as much in their footnote 12 (Pls. Br. at 14), admitting that the precedent Bard relies on "preempt[s] warning claims."[13]

Breach of Warranty (Counts X, XI). Plaintiffs allege breach of both express and implied warranties. (Compl. ¶¶ 239, 243.) "[E]xpress warranty claims would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements." *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008). Implied warranty claims contradict FDA's determination that Bard complied with all requirements, and provided all labeling, that FDA deemed sufficient to "provide a

[12] Contrary to Plaintiffs' assertion, (Pls. Br. at 25), FDA mandated specific language in many of Bard's labeling and promotional materials, (*see, e.g.*, Defs. SSOF ¶ 80), explicitly for safety reasons. *See* 21 U.S.C. §360c(i)(1)(E) (emphasis added) (FDA "may require a statement in labeling . . . if, . . . there is a reasonable likelihood that the device will be used [off-label]; and ***that such use could cause harm***.").

[13] Other information-based claims (Counts VIII, XII, XIV) are expressly preempted for the same reasons. (Compl. ¶¶ 227, 246-54, 261-62, 271.) These claims would require Bard to change its labeling and advertisements to include different or additional information beyond what FDA reviewed and found sufficient.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

reasonable assurance of the safety and effectiveness of the device." (Ex. H, at BPV-17-01-00262285); *Sprint Fidelis*, 592 F. Supp. 2d at 1164 ("[T]he plaintiff's claim for breach of implied warranty [would] impose safety and effectiveness requirements that are different from, or in addition to, those established under FDA regulations."); *see also Thibodeau*, 2014 WL 3700868, at *5 ("Claims for breach of express and implied warranties are widely held to be preempted.").

Failure to Recall/Retrofit (Count VI). Plaintiffs allege that Bard's IVC filters "are misbranded and adulterated . . . making them subject to corrective action, including recall" and that Bard breached a "duty to recall and/or retrofit." (Compl. ¶¶ 203-208.) Plaintiffs offer no federal requirement obligating Bard to recall or retrofit its IVC filters. Without any specific federal requirement, "Plaintiffs seek to impose conditions on [Bard] 'different from, or in addition to' those under federal law." *Sprint Fidelis*, 592 F. Supp. 2d at 1162. Further, "it is the FDA's task to determine whether medical devices are adulterated, and only the FDA may 'take action with respect to adulterated products.' No private cause of action exists against [Bard] for selling 'adulterated' devices, no matter how the claim may be styled." *Id*. at 1162 n.18. (recall/retrofit claims preempted).[14]

Derivative Claims (Counts XV, XVI, XVII). Plaintiffs' derivative claims for loss of consortium, wrongful death, survival, and punitive damages fail because they cannot exist without the substantive claims that are preempted. *See, e.g.*, *Sprint Fidelis*, 592 F. Supp. 2d at 1165 (derivative claims preempted).[15]

[14] Recall/retrofit claims are also impliedly preempted, for two reasons. First, these claims are not recognized under state law, *Restatement (Third) of Torts, Products Liability* §11, comment a (1998), so they amount to private FDCA enforcement barred by *Buckman*, 531 U.S. at 341. *See Arvizu*, 41 F. Supp. 3d at 793 ("Allowing Plaintiffs' claims to go forward would be essentially authorizing an impermissible action to enforce the provisions of the FDCA."). Second, these claims would impose a state-law duty not to sell devices that FDA has allowed on the market, and such "stop-selling claims" were barred "as incompatible with our pre-emption jurisprudence" in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013).

[15] Plaintiffs' negligence *per se* claim (Count IX) is expressly preempted insofar as it is predicated on alleged violations of state consumer-protection statutes. (Compl. ¶231, 278-322.) *See, e.g.*, *Degelmann*, 659 F.3d at 842 (state consumer protection and false advertising claims would impose a requirement in addition to or different from FDA requirement). If these claims depend on FDCA violations, (*see* Compl. ¶231), they are impliedly preempted. *Thibodeau*, 2014 WL 3700868, at *5; *Ramirez v. Medtronic Inc.*,

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

G. Plaintiffs' State Law Claims Are Impliedly Preempted.

Plaintiffs' claims are, alternatively, impliedly preempted. The Supreme Court explicitly rejected Plaintiffs' argument that a strong presumption against implied preemption arises because of the express preemption provision under §360k(a) of the MDA. (Pls. Br. at 26-27.) In *Buckman*, the Court held that:

> Respondent also suggests that we should be reluctant to find a pre-emptive conflict here because Congress included an express pre-emption provision in the MDA. To the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion . . . that **neither an express preemption provision nor a saving clause "bar[s] the ordinary working of conflict pre-emption principles."**

Buckman, 531 U.S. at 352 (citation omitted) (emphasis added).

Also incorrect is Plaintiffs' argument that the Supreme Court rejected implied preemption in *Lohr*. (Pls. Br. at 27.) *Lohr* only decided express preemption under the now-superseded 510(k) process in place in 1982. 518 U.S. at 501. A plurality in *Lohr* specifically contemplated that state-law claims not expressly preempted could "be preempted under conflict pre-emption analysis." *Id.* at 503. This is such a case.

As discussed, the SMDA added to 510(k) the same "reasonable assurance" of "safety and effectiveness" standard held preemptive in *Lohr* and *Riegel*. The extensive record details how FDA addressed safety and effectiveness during the 510(k) review for these products. Plaintiffs' reliance on cases that did not examine the post-SMDA 510(k) regulatory process, and instead relied on the outdated process in *Lohr*, is unavailing. *See, e.g.*, *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 485 (S.D. W. Va. 2015); *In re Depuy Orthopedics Pinnacle Hip Implant Prods.*, No. 3:11-cv-03590-K, 2014 WL 3557392, at *10-11 (N.D. Tex. July 8, 2014).

Plaintiffs' attempt to limit the implied preemption principles established in

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961 F. Supp. 2d 977, 1000 (D. Ariz. 2013) (negligence *per se* claim premised wholly on violations of the FDCA impliedly preempted). Negligence *per se* raises precisely the type of state-law claim *Buckman* held preempted, because such claims "exist solely by virtue" of the FDCA, and have FDA violations as a "critical element." 531 U.S. at 353. *But see McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1041 (9th Cir. 2015) (allowing negligence *per se* claims based on violations of FDCA). *McClellan* is contrary to the Supreme Court's holding in *Buckman*, and did not mention *Buckman*'s limitations on FDCA-based claims.

Mensing, 564 U.S. at 604, and *Bartlett*, 133 S. Ct. at 2466, to generic drugs also fails. The Supreme Court's analysis cannot be so limited, as it was grounded in universally applicable implied preemption principles. *See Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 703-04 (3d Cir. 2016) (applied to airplanes); *cf. Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204-05 (9th Cir. 2002) (applying *Buckman* implied preemption to fraud on EPA allegations).[16]

Like the drugs in *Bartlett*, 133 S. Ct. at 2470-71, Bard's IVC filters went through a rigorous PMA-like process. Also, just as the FDCA prohibited manufacturers in *Mensing* and *Bartlett* from unilaterally changing their drugs' design or labeling without prior FDA review, Bard could not make design or labeling changes that would "significantly" affect its devices' safety and effectiveness without prior FDA review and clearance. *See* 21 C.F.R. §807.81(a)(3); (Defs. SSOF ¶ 38). Plaintiffs' argument that Bard could have used "any alternative that would pass the FDA's 510(k) equivalency review," (Pls. Br. at 29), concedes that FDA review must occur first.[17] That a design might "pass" 510(k) review does not allow Bard to avoid regulatory review altogether. Plaintiffs would require Bard to violate federal law. The federal requirement of prior FDA review and clearance makes it impossible for Bard to comply with conflicting state-law duties to change the labeling or design of its IVC filters. Accordingly, Plaintiffs' claims are impliedly preempted.

III. CONCLUSION

For these reasons, Defendants request that this Court grant Defendants' Motion.

[16] Plaintiffs' citation of a single case involving insecticides regulated under FIFRA is inapposite. *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270 (D. Haw. 2015), held that *Mensing* and *Bartlett* were inapplicable because the Supreme Court's opinion in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), controlled as it "addressed the very same statute and issues before this court." *Id.* at 1285. Moreover, because *Mensing* and *Bartlett* also address the FDCA, under the "same statute" reasoning in *Ansagay*, *Mensing* and *Bartlett* control this case.

[17] Even if Bard could have changed all its IVC filters to resemble its Simon Nitinol Filter ("SNF"), (Pls. Br. at 29), such changes would still require prior FDA review. Additionally, the SNF, a permanent only IVC filter, is not a reasonable alternative to Bard's retrievable IVC filters. Finally, Plaintiffs' argument that "Bard could have made a safer product in the first instance," is a "never-start selling" claim preempted for the same reasons that *Bartlett* preempts "stop-selling claims." *See, e.g., Yates v. Ortho-McNeil-Janssen Pharms. Inc.*, 808 F.3d 281, 299-300 (6th Cir. 2015).

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

RESPECTFULLY SUBMITTED this 28th day of September, 2017.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Attorney for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of September 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000